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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/619,088

07/14/2003

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AMO0007

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07/20/2009

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EXAMINER

KOHARSKI, CHRISTOPHER

ART UNIT

PAPER NUMBER

3763

MAIL DATE

DELIVERY MODE

07/20/2009

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

DETAILED ACTION

Acknowledgements

The Examiner acknowledges the reply filed 4/20/2009 in which claims 77, 109, 119, 128, and 137 were amended. Currently claims 77-86 and 109-148 are pending for examination in this application.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 77, 80-86, 109, 112-116, 119, 122-125, 128, 130-134, 137-139, and 141-146 are rejected under 35 U.S.C 103(a) as being unpatentable over Bylsma (USPN6,319,220) in view of Dotson, Jr. (USPN4,274,411).

Regarding claims 77, 80-86, 109, 112-116, 119, 1212-125, 128, 130-134, 137-139, and 141-146, Bylsma discloses a method and device for aspirating fluid from an ocular region during a phacoemulsification procedure (cols 2, 30-70; col 3, ln 1-30)

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comprising aspirating (4) the ocular region via a tubing deforming pressure system (17, peristaltic pump and tub 14) to the ocular region via fluid control device (10) while applying ultrasonic energy with a needle (34), capable of producing cavitation (Figures 7-9). Bylsma further discloses delivering modulated ultrasound (see Figures 6-7)(col 4, In 10-40) using an ultrasound phacoemulsification hand piece (30) (Figure 1).

Bylsma meets the claim limitations as described above except for the specific fluid control device creating a pressure pulse system for aspiration.

However, Dotson, Jr. discloses a fluid operated ophthalmic irrigation and aspiration device.

Regarding claims 77, 80-86, 109, 112-116, 119, 122-125, 128, 132-134, 137-139, and 141-146, Dotson, Jr. discloses a fluid operated method and device for aspiration of the ocular region (see abstract) using modulated differential pressure pulses (pulse mode, moving from no vacuum to a the preset vacuum level, via control 29 and selector 30) via a fluid control device (Figures 1-3) (col 1, In 50-67) (col 5, In 15-55).

At the time of the invention, it would have been obvious to use the aspiration control system of Dotson, Jr. with the system of Bylsma in order to provide a system that aids in the aspiration of hard to remove pieces of material (cols 1, In 60-70) and the system of Dotson, Jr. is disclosed to be used with numerous types of hand piece systems (col 3, In 1-20). Further it well within the ordinary skill of the art to combine the pulsed vacuum system of Datson, Jr. to the system of Bylsma, as taught by each reference to include the benefits of pulsed actions provide superior operation whether it

be in irrigation, ultrasound power, or vacuum control. The references are analogous in the art and with the instant invention; therefore, a combination is proper. Therefore, one skilled in the art would have combined the teachings in the references in light of the disclosure of Dotson, Jr. (cols 1-2).

Claim Rejections - 35 USC § 103

Claims 78-79, 85-86, 110-111, 117-118, 120-121, 126-127, 129-131, 135-136, 140-141 and 147-148 are rejected under 35 U.S.C 103(a) as being unpatentable over Bylsma (USPN6,319,220) in view of Dotson, Jr. (USPN4,274,411)

The modified Bylsma discloses the claimed invention except for the specific modulation pulse duration (100 milliseconds, 8 milliseconds, and 25, milliseconds).

Regarding claims 78-79, 85-86, 110-111, 117-118, 120-121, 126-127, 129-131, 135-136, 140-141 and 147-148, it would have been obvious to one having ordinary skill in the art at the time the invention was made to use the duration values as claimed by Applicant since the values as claimed lack criticality for the specific pulse times and duration and since Dotson, Jr. discloses the duration and pulse amounts can be varied to optimize removal of fragments (col 6, ln 20-60); additionally, it has been held that discovering an optimum value of a result effective variable involves only routine skill in the art. *In re Boesch*, 617 F.2d 272, 205 USPQ 215 (CCPA 1980). See Gonan (6,423,028) for representative example illustrating varied pulse durations (Figures 1-10, col 4).

Response to Arguments

Applicant's arguments filed 4/20/2009 have been fully considered but they are not persuasive. Applicant's Representative asserts that the combination of Bylsma in view of Dotson does not disclose the limitation such as **"...applying modulated differential fluid pressure pulses to the ocular region via a tubing deformation fluid control device and substantially close aspiration tubing to selectively..."** and uses hindsight and is an improper combination of references.

Examiner has fully considered applicant's arguments but they are not persuasive. It is examiners position that given a careful reading, the claims do not distinguish over the prior art of record.

Examiner asserts that the references meet the claimed limitations of the pending claims. The Examiner asserts that the Bylsma reference discloses an aspiration system (Figure 1) comprising an aspiration tube (4) and peristaltic pump (17) which acts of the tubing via deformation to create the aspiration action through the tubing (4) to deliver the fluid into the waste bag (5). The peristaltic pump is used to generate the aspiration force and completes this task via tubing deformation. The Datson, Jr. reference is merely used to teach the use of a pulsed aspiration system, this teaching can be applied to the system of Bylsma by replacing the foot controlled pedal (40) with the fluid controller of Datson, Jr. to control the peristaltic pump (17) that deforms the tubing. Therefore, the combination of Bylsma and Datson, Jr. discloses "...applying modulated differential fluid pressure pulses (fluid controller of Datson, Jr.) to the ocular region via a

tubing deformation fluid control device (peristaltic pump of Bylsma) and substantially close aspiration tubing to selectively (via pump tube deformation)..."

In response to Applicant's argument that the examiner's conclusion of obviousness is based upon improper hindsight reasoning, it must be recognized that any judgment on obviousness is in a sense necessarily a reconstruction based upon hindsight reasoning. But so long as it takes into account only knowledge which was within the level of ordinary skill at the time the claimed invention was made, and does not include knowledge gleaned only from the applicant's disclosure, such a reconstruction is proper. See *In re McLaughlin*, 443 F.2d 1392, 170 USPQ 209 (CCPA 1971). Regarding the combination of references, the Examiner has clearly articulated the reason (see above rejection) to which one of ordinary skill in the art would apply. Both references describe that the pulsed modes allow for optimal use and extraction of tissue. The Bylsma reference discloses a system with pulsed ultrasonic properties and the advantages thereof (cols 1-2), while the Dotson, Jr. reference discloses an aspiration system commonly used with ultrasound systems (35, col 1) with a pulsed aspiration mechanism and the advantages thereof (col 1, 60-70). It is well within the ordinary skill of the art to combine the pulsed vacuum system of Dotson, Jr. to the system of Bylsma, as taught by each reference to include the benefits of pulsed actions provide superior operation whether it be in irrigation, ultrasound power, or vacuum control.

The prior art of record teaches all elements as claimed and these elements satisfy all structural, functional, operational, and spatial limitations currently in the claims. Therefore the standing rejections are proper and maintained.

Suggested Subject Matter

The following claim subject matter is suggested by the examiner and considered to distinguish patentably over the art of record in this application and is therefore presented to Applicant for consideration:

Examiner suggests further clarification to the pulse procedure or structural elements that define the aspiration control components (valve body on tubing) as shown in Figures 14A-14B.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christopher D. Koharski whose telephone number is 571-272-7230. The examiner can normally be reached on 5:30am to 2:00pm EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nick Lucchesi can be reached on 571-272-4977. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Date: 7/14/2009

/Christopher D Koharski/
Examiner, Art Unit 3763

/Nicholas D Lucchesi/
Supervisory Patent Examiner, Art Unit 3763